

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Office of the Secretary

Departmental Appeals Board, MS 6127
 Medicare Appeals Council
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Docket Numbers: M-19-3032 & M-20-74

ALJ Appeal Number: 3-8473385300

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NOTICE OF CONSOLIDATED DECISION OF MEDICARE APPEALS COUNCIL**What This Notice Means**

Enclosed is a copy of the decision of the Medicare Appeals Council. If you have any questions, you may contact the Centers for Medicare & Medicaid Services regional office or the local Medicare contractor.

Your Right to Court Review

If you desire court review of the Council's decision and the amount in controversy is \$1,760 or more, you may commence a civil action by filing a complaint in the United States District Court for the judicial district in which you reside or have your principal place of business. See § 1869(b) of the Social Security Act, 42 U.S.C. § 1395ff(b). The complaint must be filed within sixty days after the date this letter is received. 42 C.F.R. § 405.1130. It will be presumed that this letter is received within five days after the date shown above unless a reasonable showing to the contrary is made. 42 C.F.R. § 405.1136(c)(2).

If you cannot file your complaint within sixty days, you may ask the Council to extend the time in which you may begin a civil action. However, the Council will only extend the time if you provide a good reason for not meeting the deadline. Your reason must be set forth clearly in your request. 42 C.F.R. § 405.1134.

If a civil action is commenced, the complaint should name the Secretary of Health and Human Services as the defendant and should include the Council's docket number and ALJ appeal number shown at the top of this notice. 42 C.F.R. § 405.1136(d). The Secretary must be served by sending a copy of the summons and complaint by registered or certified mail to the General Counsel, Department of Health and Human Services, 200 Independence Avenue, S.W., Washington, D.C. 20201. In addition, you must serve the United States Attorney for the district in which you file your complaint and the Attorney General of the United States. *See* rules 4(c) and (i) of the Federal Rules of Civil Procedure and 45 C.F.R. § 4.1.

This notice and enclosed order were mailed on: April 26, 2021.

Enclosure

cc: Beneficiary
Q2A AdQIC Records Management

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD
Medicare Appeals Council
Docket Nos. M-19-3032 & M-20-74

M.R. & Novocure, Inc., Appellants
ALJ Appeal No. 3-8473385300

CONSOLIDATED DECISION

The Administrative Law Judge (ALJ) issued a decision dated September 16, 2019, concerning Medicare Part B coverage of an Optune device rental, which delivers Tumor Treatment Field Therapy (TTFT) (HCPCS code E0766), furnished to the beneficiary from October 16, 2018, through December 16, 2018. The ALJ found that Medicare does not cover the device and held the supplier financially responsible for the non-covered costs.¹

The beneficiary, through an appointed representative, filed a request for review, seeking Medicare Appeals Council (Council) review of the ALJ's action. We enter the beneficiary's request for review into the record as Exhibit (Exh.) MAC-1. The docket number for this case is M-19-3032. The supplier subsequently filed a separate request for review, which adopted the beneficiary's contentions. We enter the supplier's request for review as Exh. MAC-2. The docket number for this case is M-20-74.

The Council reviews the ALJ's action *de novo*. 42 C.F.R. §§ 405.1100, 405.1108(a). Our review is limited to the exceptions raised by the appellants in the requests for review. *Id.* § 405.1112(c). For the reasons set forth below, we agree with the ALJ that Medicare does not cover the Optune device and that the supplier is financially responsible for the non-covered costs. Therefore, we adopt the ALJ's decision.

BACKGROUND AND PROCEDURAL HISTORY

At issue in this case is Medicare coverage of an Optune device rental furnished to the beneficiary from October 16, 2018, through December 16, 2018, for TTFT of her newly diagnosed glioblastoma multiforme (GBM). *See* File 1 at 3-5, 42-43; File 6 at 20, 25; Hearing CD. The ALJ denied coverage because Local Coverage Determination (LCD)

¹ In the Conclusions of Law, the ALJ stated the beneficiary was liable for the non-covered costs; however, this appears to be a scrivener's error. ALJ Decision at 12. In the immediately preceding analysis, the ALJ found the record did not contain evidence that the beneficiary had notice of non-coverage and further found the supplier had constructive notice of non-coverage, holding the supplier liable for the non-covered items. *Id.* at 11-12.

L34823 (Effective Jan. 1, 2017), to which he gave substantial deference, states that Medicare will deny coverage of TTFT as not medically reasonable and necessary. *See* Decision (Dec.) at 10-11. The ALJ held the supplier financially responsible for the non-covered costs. *Id.* at 11-12.

Before the Council, the beneficiary raises several contentions. The beneficiary states that, on May 28, 2019, the Departmental Appeals Board (DAB)'s Civil Remedies Division (CRD) ruled that the LCD record did not support the LCD's validity. Exh. MAC-1 at 2-3. The beneficiary contends the Medicare contractor has since revised the LCD, which is the same as a judicial ruling that the LCD is invalid. *Id.* The beneficiary further contends that the revised LCD L34823, effective September 1, 2019, extends coverage to newly diagnosed GBM. *Id.* The beneficiary states that prior ALJ decisions granted coverage to the beneficiary and, therefore, the doctrine of collateral estoppel precludes the Secretary of the U.S. Department of Health & Human Services from denying coverage in this case. *Id.* at 5-6. The beneficiary also contends that Medicare should cover TTFT because the peer-reviewed literature, clinical trials, FDA approval, and National Comprehensive Cancer Network guidelines show that TTFT is safe, effective, and widely accepted by the medical community. *Id.* at 3. Lastly, the beneficiary contends that the ALJ failed to conduct a *de novo* review of the case. *Id.* at 4-5. The beneficiary maintains that TTFT is a life-saving form of treatment for this type of brain cancer and has conferred a specific benefit to her. *Id.* at 5. The supplier does not raise any additional contentions. Exh. MAC-2.

As a preliminary matter, we address the beneficiary's contention that the doctrine of collateral estoppel precludes the Secretary from re-litigating coverage of TTFT in this case because ALJs previously found that TTFT is medically reasonable and necessary for the beneficiary, and the Secretary did not appeal those decisions. Exh. MAC-1 at 5-6. The fact that other ALJs may have decided in the beneficiary's favor is irrelevant because, as a district court explained, the "Medicare regulations reveal an administrative review structure incompatible with applying collateral estoppel at the agency level." *Christenson v. Azar*, No. 20-C-194, 2020 WL 3642315 at *5 (E.D. Wis. July 6, 2020); *see also Almy v. Sebelius*, 679 F.3d 297, 310 (4th Cir. 2012) ("[I]t is undisputed that these lower-level decisions are not precedential and not binding on the [Council]. . . . There is no authority for the proposition that a lower component of a government agency may bind the decision making of the highest level.") (internal citations omitted). Thus, we find that the application of collateral estoppel is not appropriate in this case.

DISCUSSION

TTFT is not medically reasonable and necessary for the claims at issue.

We have considered the beneficiary's contentions and the circumstances presented in this case, including the adjudication of the LCD's validity in a separate matter and the

revision of the LCD. We find no basis under the arguments and evidence proffered not to give substantial deference to LCD L34823, effective January 1, 2017, which sets forth the Centers for Medicare & Medicaid Services' (CMS) determination that, for dates of service at issue, TTFT is not medically reasonable and necessary.

Pursuant to § 1862(a)(1)(A) of the Social Security Act (Act), Medicare only covers items and services that are medically reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the function of a malformed body member. In accordance with § 1862(a)(1)(A), Medicare administrative contractors may issue LCDs, which are determinations on whether a particular item or service is medically reasonable and necessary or covered by Medicare. Act § 1869(f)(2)(B). LCDs do not bind ALJs or the Council but ALJs and the Council must give an LCD substantial deference if it is applicable to a particular case. 42 C.F.R. § 405.1062(a). If an ALJ or the Council declines to follow an LCD, the decision must explain the reasons why the ALJ or the Council departed from the LCD and why it does not have precedential effect. *Id.* § 405.1062(b). Neither an ALJ nor the Council has the authority to set aside or review the validity of an LCD for purposes of a claim appeal. *Id.* § 405.1062(c).

We emphasize that CMS, not the Council or ALJs, sets the coverage policy for medical services and items, as it has done for TTFT through the LCD process. The Council's jurisdiction is to adjudicate claims for services and items under Medicare coverage rules and CMS policies, and other actions that are initial determinations. *See id.* § 405.924. In doing so, the Council and ALJs will give substantial deference to an applicable LCD but may decline to follow the LCD based on the facts of a particular case. *Id.* § 405.1062. Importantly, the authority to depart from an LCD is limited to the facts of a particular case because there is a separate process for challenging the underlying validity of an LCD, which may affect other beneficiaries. *See* Act § 1869(f)(2)(A) (creating the LCD review process); 68 Fed. Reg. 63692, 63693-63694 (Nov. 7, 2003) (discussing the differences between the claims appeals process and the LCD review process).

Relevant here, the Medicare administrative contractor with jurisdiction over the beneficiary's geographic area issued LCD L34823, effective Jan. 1, 2017. The LCD explicitly states that TTFT, billed under HCPCS code E0766, "will be denied as not reasonable and necessary." LCD L34823. Under the circumstances of this case, we find that it is appropriate to defer to this version of LCD L34823 for the dates of service at issue. *See* 42 C.F.R. § 405.1062.

The beneficiary contends that the CRD ruled the "LCD record did not support the validity of the LCD under the reasonableness standard." Exh. MAC-1 at 2-4; *see* File 14 at 42-46. We acknowledge that the LCD was the subject of an LCD complaint before an ALJ, but the CRD has since dismissed the complaint because the contractor removed the categorical prohibition on coverage by revising the LCD. *See In re LCD Complaint: Tumor Treatment Field Therapy LCD ID Number: L34823, DAB CR5546 (2020).* Under

the regulations, revising “an LCD under review to remove the LCD provision in question has the same effect as a decision under § 426.460(b),” *i.e.*, that it is invalid. 42 C.F.R. § 426.420(b). However, the regulations are clear that only the “party who challenged the LCD” will receive an individual claim review without using the invalidated LCD, not all parties with pending claims. *Id.* § 426.460(b)(1). Furthermore, the regulations state that any change in policy “applies *prospectively* to requests for service or claims filed with dates of service after the implementation of the ALJ decision.” *Id.* § 426.460(b)(2) (emphasis added); *see* 68 Fed. Reg. at 63712 (“[T]he retirement of a coverage determination or removal of a provision of a coverage determination means that it can no longer be used in the adjudication of claims with dates of service after the effective date of the ALJ/Board decision.”). Thus, we find that the version of LCD L34823 in effect for the dates of service at issue, which was prior to the CRD’s dismissal, remains applicable.

The beneficiary notes that the Medicare contractor issued a revised LCD, following the LCD challenge. Exh. MAC-1 at 2-3. We acknowledge that the contractor issued a revised LCD, effective September 1, 2019, which allows coverage of TTFT for newly diagnosed GBM, if certain coverage criteria are satisfied. LCD L34823 (Effective Sept. 1, 2019). However, there is no indication that Medicare contractors and adjudicators should apply the revised LCD retroactively. *See id.* Rather, as discussed above, and consistent with the regulations, the LCD applies *prospectively* to claims on or after its effective date. *See* 42 C.F.R. § 426.460(b)(2); 68 Fed. Reg. at 63705 (stating that LCD changes “can only be applied prospectively to requests for payment,” and therefore, “regardless of subsequent policy changes, for purposes of reconsidering a payment determination, the relevant LCD/NCD is the policy in effect at the time the item or service was provided.”). We acknowledge that the beneficiary is potentially in the position of not benefiting from the LCD challenge or the LCD revision simply based on the dates of service, but these are the procedures and implementation timelines set forth in the regulations. We emphasize again that CMS makes the coverage policy and, as it currently stands, the policy set forth in the LCD is that coverage is only available for TTFT treatment provided on or after September 1, 2019 (absent a showing of particular circumstances to depart from that policy).

The beneficiary also contends that Medicare should cover the Optune device because the peer-reviewed literature, regulatory approval, and consensus of experts show that the device is medically reasonable and necessary. Exh. MAC-1 at 3. The beneficiary further contends that the medical community has accepted TTFT as being safe and effective. *Id.* This argument is, in effect, a challenge to the validity of LCD L34823, effective Jan. 1, 2017, because the beneficiary is arguing that the LCD’s evidentiary sources are inadequate and incomplete, and thus, do not sufficiently support the determination that TTFT is not reasonable and necessary.

Congress, however, has created a separate appeals process for challenging the validity of LCDs. Act § 1869(f)(2)(A); *see also* 42 C.F.R. § 426.100. In an LCD challenge, an ALJ

and/or the DAB reviews the LCD record, which consists of any document or material that the contractor considered during the development of the LCD and, applying the reasonableness standard, determines whether the record is complete and adequate to support the validity of the LCD. 42 C.F.R. §§ 426.418, 426.419. Thus, in the claims appeals process, we may not decline to follow an LCD because its evidentiary support may be outdated or contradicted by the medical community or peer-reviewed literature. *Id.* § 405.1062(c).

The beneficiary further contends that she is entitled to a *de novo* determination on whether substantial deference should be given to the LCD based on the facts of the case and the arguments presented. Exh. MAC-1 at 3-5. However, the beneficiary has not identified any particular facts specific to her and her circumstances in contending that substantial deference should not be given to the LCD, nor does the beneficiary cite to the administrative record to support her position. *See generally* Exh. MAC-1. The beneficiary is essentially asking the Council not to apply the policy because TTFT for the treatment of GBM is the standard of care supported by the medical community, which would apply to all beneficiaries seeking this treatment. Not to defer to the LCD for these reasons would substitute the Council as policy makers, which is outside of our authority. Therefore, we find no basis for departing from the LCD under the standard set forth in the regulations. *See* 68 Fed. Reg. at 63,693.

Finally, we acknowledge the beneficiary's contention that the ALJ erred by failing to conduct a *de novo* review of the entire administrative record. Exh. MAC-1 at 4-5. We disagree. Here, the ALJ concluded that substantial deference was owed to the applicable LCD because the arguments and evidence proffered in this appeal did not provide a basis to decline to follow the LCD, a conclusion with which we agree. *Id.*

In sum, finding no reason not to defer to LCD L34823, effective Jan. 1, 2017, we conclude that Medicare does not cover the Optune device rental, which delivers TTFT, during the dates of service at issue.

The supplier is financially responsible for the non-covered costs.

Section 1879 of the Act creates a limitation on liability when a beneficiary or supplier did not know, and could not reasonably have been expected to know, that Medicare would not cover the items or services at issue. Neither the beneficiary nor the supplier has raised an objection to the ALJ's conclusion that the supplier, and not the beneficiary, is financially responsible for the non-covered costs under § 1879. Thus, we adopt the ALJ's finding, and the supplier remains financially responsible for the non-covered costs. *See* 42 C.F.R. § 405.1112(c).

DECISION

For the reasons set forth above, the Council adopts the ALJ's decision. We find that Medicare Part B does not cover the Optune device used for the delivery of TTFT, which the supplier furnished to the beneficiary on a rental basis from October 16, 2018, through December 16, 2018. The supplier is financially responsible for the non-covered costs.

MEDICARE APPEALS COUNCIL



Debbie K. Nobleman
Administrative Appeals Judge

Date: April 26, 2021